DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-401/S-013 **OCT 1 6 1998**

Biovail Laboratories Incorporated
c/o Keller and Heckman
Attention: Mr. John Dubeck
Suite 500 West 1001 G Street, N.W.
Washington, DC. 20001

Dear Mr. Dubeck:

Please refer to your supplemental new drug application dated February 27. 1998, received March 2, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tiazac (diltiazem HCI) Capsules.

We acknowledge receipt of your submissions dated August 31 and September 15 (two), 1998. Your submissions of September 15, 1998 constituted a full response to our August 28, 1998 action letter.

This supplemental new drug application provides for a new dosage strength, 420 mg Capsules.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and immediate container and carton labels submitted September 16, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research